

REMARKS/ARGUMENTS

Reconsideration is requested. Claims 1 - 27 are pending. Responsive to the Office Action of July 31, 2007, the Examiner's comments and the cited art have been noted and studied. For reasons to be set forth in detail below, it is respectfully submitted that the present application is in condition for allowance, and such action is requested.

For clarity and to expedite allowance, independent claims 1, 13 and 19 have been amended. In particular, claims 1, 13 and 19 now recite that the skin-piercing element is "configured for penetrating into dermal tissue," that the electrical contact is an "electrical outer skin pressure contact" and that the electrical characteristic is measured "through the dermal tissue" and is "indicative of dermal tissue penetration depth by the skin-piercing element." Support at, for example, original claims 2, 3 and 18; paragraphs 00019, 00023, 00026 and 00034; and FIGs. 6 and 12 of the original disclosure. Accordingly, dependent claims 2, 3 and 18 have been canceled.

Claims 4-8, 10, 14, 15, 24 and 25 have been amended for consistency.

It is respectfully submitted that the amendments above are supported by the specification, claims, abstract of the disclosure, and drawings as originally filed, and that no new matter has been added.

Claim Objections

Claims 1, 13, 18 and 24 were objected to for consistency. Applicants submit that claims 1, 13, and 24, as amended, are consistent and not subject to objection. Claim 18 has been canceled.

Claim Rejections under §102

The subject matter of claims 1-7, 10-12, and 19-25 was rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent Application Publication US2003/0083641 to Angel et al. (hereinafter "Angel").

Angel, as understood, describes a transdermal transport device with an impedance sensor for measuring impedance between a needle that penetrates skin and an electrode (see, for example, paragraph 0010 of Angel). The electrode of Angel is also a microneedle that

penetrates the skin (see paragraph 0045 of Angel). The impedance sensor measures impedance between the two microneedles (element 14 of Angel), both of which are penetrating the skin (see, for example, FIG. 2A and paragraph 0045 of Angel).

Independent claims 1 and 19 each recite that an electrical characteristic is measured between a skin-piercing element and an electrical outer skin pressure contact. The electrical outer skin pressure contact recited in these amended claims, by definition, does not penetrate the dermal tissue and is, therefore, distinguished over the microneedle electrode of Angel. The provision and use of an electrical outer skin pressure contact provides the unobvious benefits of, for example, enabling integration of the contact into a pressure/contact ring and a compact design (see, for example, paragraphs 0008, 00026 and 00027 of the original disclosure). Angel does describe, teach or suggest such an electrical outer skin pressure contact, its use or its benefits.

For at least the foregoing reasons, Applicants respectfully submit that amended independent claims 1 and 19 are allowable over Angel. Since dependent claims necessarily contain the limitations of their parents, dependent claims 2-7, 10-12, and 20-25 are allowable for at least the same reasons.

The subject matter of claims 1, 8, 9, 13-14, and 18 was rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent Application Publication US2003/0216661 to Davies (hereinafter "Davies").

Davies appears to describe a handheld probe configured to measure DC electropotential and impedance employing, for example, a nipple electrode, intravenous electrode, or skin surface electrode (see, for example, paragraph 0065 of Davies). The probe is configured to make medical diagnosis measurements related to the functional state of tissue and the detection of malignancy (see, for example, paragraphs 0025 and 0070 of Davies).

There appears to be no description, teaching or suggestion in Davies related to a sensor configured for measuring an electrical characteristic that is indicative of dermal tissue penetration depth by a skin-piercing element as is recited in amended independent claims 1 and 13. Rather, the probe of Davies is configured to measure characteristics related to tissue functional states and malignancy.

For at least the foregoing reasons, Applicants respectfully submit that amended independent claims 1 and 19 are allowable over Davies. Since dependent claims necessarily contain the limitations of their parents, dependent claims 8, 9, and 14 are allowable for at least the same reasons (noting that claim 18 has been canceled).

Claim Rejections under §103

The subject matter of claims 13, 15-17 and 26 were rejected under 35 USC §103(a) as obvious over Angel in view of U.S. Patent Application Publication US2002/0065481 to Cory et al. (hereinafter "Cory").

The deficiencies of Angel have been discussed above. Cory describes a system and method for depth determination that employs a resistance measurement of a needle coating that protrudes above the skin surface (see, for example, paragraphs 0053 and 0054 of Davies).

Since the current claims recite a sensor or step that measures "an electrical characteristic existent between a skin-piercing element and electrical outer skin pressure contacts *through the dermal tissue* that is indicative of dermal tissue penetration depth by the skin-piercing element," (emphasis added) they are distinguished over the measurement of the resistance of a needle coating protruding *above a surface* as described by Cory.

For at least the foregoing reason, Applicants respectfully submit that amended independent claim 13 and dependent claim 26 are allowable over the combination of Angel and Cory. Since dependent claims necessarily contain the limitations of their parents, dependent claims 15-17 are allowable for at least the same reason.

The subject matter of dependent claim 27 was rejected under 35 USC §103(a) as obvious over Angel in view of U.S. Patent No. 5,069,223 to McRae (hereinafter "McRae").

The deficiencies of Angel with respect to independent claim 19 were detailed above. McRae was cited for frequency range teachings and does not cure the deficiencies of Angel. Therefore, for at least the foregoing reason Applicants respectfully submit that dependent claim 27 is allowable over the cited combination of Angel and McRae.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance and applicant earnestly solicits early examination on the merits and issuance of a Notice of Allowance. Should the Examiner believe that any additional information or amendment is necessary to place the application in condition for allowed, he is urged to contact the undersigned Attorney via telephone at 408-956-4790.

The Commissioner is hereby authorized to charge any required fees due in connection with this submission, including petition and extension of time fees, and to credit any overpayment to Deposit Account No. 10-0750 (Docket No. LFS5004/MM (Johnson & Johnson)).

Respectfully submitted,

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